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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,759	10/14/2003	Li Wang	P11118.00	3360

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MEDTRONIC, INC.
710 MEDTRONIC PARK
MINNEAPOLIS, MN 55432-9924

EXAMINER	
ALTER, ALYSSA M	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/684,759	WANG ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62 and 65-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,17-20,22,24-36,40-43,45,47-55,59-62,65,66,70 and 71* is/are rejected.

7)☐ Claim(s) *14-16,21,23,37-39,44,46,56-58 and 67-69* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-62 and 65-71 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 4-7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4-7 recites the limitation "pulse of energy" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-13, 17-20, 22, 24-36, 40-43, 45, 47-55, 59-62, 65-66 and 70-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimchi et al. (US 6,360,123) in view of Ho et al. (US Patent Publication 20030220578 A1). Kimchi et al., as previously made of record, discloses an impedance sensor disposed within a blood vessel. The impedance sensor has at least two electrodes to determine the electrical

impedance and obtain an impedance signal correlated with the mechanical property of the heart. Since the electrodes record the impedance, they are obviously measuring at a time point relative to a cardiac cycle.

Kimchi et al. further discloses "the impedance measuring unit and the impedance sensor may be adapted for using various impedance measuring methods known in the art" (col. 3, lines 5-7) and "additional methods and devices for impedance determination which are more resistant to electrical noise and to tissue myo-electric variations or other property variations are known in the art (col. 8, lines 46-49)"

While Kimchi et al. does discloses the employment of other known methods and devices for impedance determination, specifically ones which are more resistant to electrical noise and tissue myo-electric variations, Kimchi et al. does not disclose the impedance measurements being cardiac-gated impedance measurements.

Therefore, Kimchi et al. discloses the claimed device except for cardiac-gated impedance measurements. Ho et al. teaches that it is known to use of cardiac-gating, which "allows appropriate referencing of images obtained over the cardiac cycle (throughout systole and diastole) in a "cine" mode. Cine MR imaging is central for illustration and/or measurement of cardiac blood flow as well as vascular blood flow in general. Furthermore, the ability to accurately perform cardiac-gated data acquisitions enables the achievement of not only sharper image detail but also higher spatial resolution images (page 1, paragraph 6)". Also, the "embodiments of the invention lead to improved image quality, more accurate imaging of cardiac and intrathoracic/upper abdominal structures and improved referencing of systemic arterial blood flow for blood

flow measurement within the chest and elsewhere in the body, including, for example, the extremities"(page 2, paragraph 16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the impedance measurements as taught by Kimchi et al. with the cardiac-gated impedance measurements as taught by Ho et al., in order to have a more accurate imaging of cardiac and intrathoracic/upper abdominal structures.

As to claim 2, Ho et al. disclose collecting "images obtained over the cardiac cycle (throughout systole and diastole)" on page 1, paragraph 6. Therefore, the modified Kimchi et al. does discloses a time point relative to the cardiac cycle being an early part of a diastolic phase, since the images are obtained throughout the diastole portion, thus including the early part of the diastolic phase.

As previously made of record:

As to claim 1, 8-9, 24, 31-32, 47, 49 and 51-52, "One possible method for determining impedance in a tissue includes passing a high frequency modulated current signal through a pair of electrodes, such as, for example the electrodes 22B and 22C of FIG. 2 and low pass filtering and demodulating the voltage signal which develops across the electrodes 22B and 22C" (col. 8, lines 26-31).

Furthermore, Kimchi et al. discloses in col. 5, lines 6-25, an impedance determining unit 14 as seen in figures 1 and 2. Within the impedance measuring unit there is obviously a mathematical means for data manipulation.

As to claims 2, 25, 48 and 50, Figures 5A-5D display graphs resulting from using the impedance determining method of the present invention. As seen in the figure 5B,

the impedance is continually measures and thus a portion is obviously measured during the entire PQRST waveform, inclusive of the refractory portion, an isovolumic phase, an early isovolumic phase, a late part of a systolic phase and an early part of a diastolic phase. Furthermore, since the rate of cardiac pressure change is recorded, there is also a minimum recorded.

As to claims 4-7 and 27-30, "The impedance measuring unit and the impedance sensor may be adapted for using various impedance measuring methods known in the art, including, but not limited to impedance determining methods using high frequency modulated currents or current pulses, and methods using various test current pulses"(). Therefore Kimchi et al. discloses the use of monophasic pulses, biphasic pulses and predetermined pulses.

As to claims 10, 13, 33, 36, 53, 55 and 66-65, the figures display electrodes, which are coil electrodes. Specifically depicted in figure 4A are coil electrodes 32B and 32C.

As to claims 11-12, 34-35 and 54, also seen in figure 2, "the organ 18 is the heart, the blood vessel 16 is a lateral branch of the great cardiac vein (GCV). The mechanical property which is determined by measuring the intra-vessel impedance is the left ventricular pressure (LVP). When the sensor 22 is disposed within a branch of the GCV, the impedance signal which is output by the impedance determining unit 14 is highly correlated to the LVP"(col. 5, lines 53-59).

As to claims 17-18, 40-41 and 59-60, "devices such as, but not limited to pacemakers or automatic internal cardiac defibrillator (AICD) devices may be equipped

with the impedance sensor and the impedance determining unit of the present invention and use them as disclosed hereinabove to monitor the LVP related impedance signal. Such a device may detect a suspected VF based on the simultaneous detection of increased heart rate sensed by an electrical sense electrode, and a flattening of the pulsatile LVP correlated impedance signal peak amplitude below a specified threshold level. Upon detection of such a suspected VF, the device may apply defibrillation pulses or other types of defibrillating therapy to the heart of the patient. Such a device may have the advantage of increasing the reliability in VF detection without adding additional leads electrodes or sensors to the device, since the impedance electrodes may be included in a pacing lead or the impedance may be measured by using existing electrodes which are also used for such purposes of sensing or pacing in the pacemaker part of the device"(col. 15, lines 1-19). Since Kimchi et al. discloses the use of pacing/sensing electrodes, obviously when the pacemaker delivers therapy then sensing is suspended and likewise when the pacemaker system is sensing, therapy is suspended.

As to claims 19-20, 42-43, 61-62, since the first electrode is separate from the second electrode, as seen in the figures the examiner considers the first electrode to be different form the second electrode and vice versa. Specifically figure 4A displays two separate coil electrodes 32B and 32C. Furthermore, Kimchi et al. discloses that an addition set of electrodes can be used, which would be different from the first pair of electrodes.

As to claims 22 and 45, Kimchi et al. discloses in col. 1, lines 43-44, the impedance measurements can be used to estimate respiratory minute ventilation.

Allowable Subject Matter

1. Claims 14-16, 21, 23, 37-39, 44, 46, 56-58 and 67-69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alyssa M Alter
Examiner
Art Unit 3762

ROBERT E. PEZZUTO
SUPERVISORY PRIMARY EXAMINER